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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,310	05/31/2001	Robert Ainsworth	3764.P180	4544

8791 7590 05/19/2006

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EXAMINER

JUNG, WILLIAM C

ART UNIT PAPER NUMBER

3768

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/872,310		AINSWORTH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	William Jung		3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-21, 32-35 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-21, 32-35, and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-5, 7-21, 32-35, and 44-46 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 5, 7-9, 1-13, 15-19, 21, 32, 34, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over *McGee et al* (US 5,752,518) in view of *Crowley et al* (US 5,372,138).

McGee et al substantially disclose all features in claims 1, 2, 5, 7-9, 1-13, 15-19, 21, 32, 34, and 44-46.

**Claims 1, 15, and 44:** McGee et al anticipate all claimed elements in claims 1, 15, 22, 26, 28, 40, and 44: McGee et al disclose an intravascular catheter 10 comprising structure 20 to perform diagnostic imaging and therapeutical treatment with sheathed optical fibers 44 disposed through the intravascular catheter. In addition, a sheath is slidably disposed over the catheter shaft and an intraluminal gap extending longitudinally along the elongated member. Furthermore, the control of the intravascular catheter is achieved with guidewire (col. 5, line 30-34). The imaging using either ultrasound transducer or fiber optic assembly can be used before and after the treatment to assess treatment area (col. 1, lines 44-67; col. 3, line 53 – col. 4, line

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39; col. 4, line 62 – col. 5, line 10). In addition, McGee et al intravascular catheter has expandable portion 64 (col. 7, lines 53-60). Further more, Mc Gee et al disclose the same limitation on col. 11, line 60 – col. 12, line 9, where the electrode 30 comprises a conductive material and spaced apart lengths of closely wound, spiral coils wrapped about the sleeve 32. However, McGee et al does not explicitly disclose that the structure of the coil-like enclosure is concentrically surrounds the at least one optical fiber and at least one optical fiber is bonded along an inner surface of the coli-like enclosure. This particular feature is well known in the art as demonstrated by Crowley et al where in figure 4 shows optical fiber is bonded to inner surface of the coil like enclosure 28 to improve shielding and structural support for the intravascular probe or catheter designed for imaging and treatment. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Crowley et al's structural improvement described above with McGee et al's teaching to achieve the claimed invention.

**Claims 32 and 34:** McGee et al further disclose in figure 6 where receiver & processor 57 processes the data and display on display unit 59.

**Claims 2 and 19:** McGee et al shows in figure 4A, where the optical fiber 20 is exposed within a vasculature of a patient.

**Claims 5, 8, 9, 12, 13, 16, 18, and 46:** McGee et al disclose that the inflatable portion 64 is a balloon catheter disposed about a tubular inner member having a lumen to receive the optical fiber 34 (col. 7, lines 52-61). The inflatable balloon can be applied in procedure such as angioplasty, stenting and restenting (col. 3, line 62 – col. 4, line 9).

**Claims 7, 11, 17, and 45:** I figures 1 and 5A McGee et al shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen. In addition, figure 5A shows that the optical fiber is substantially parallel to the tubular member.

**Claims 12 and 18:** As described above, McGee et al disclose the catheter where the lumen is consisting of guidewire, inflatable balloon, radiation source, atherectomy, laparoscopy, and drug delivery (col. 3, line 62 – col. 4, lines 9; col. 5, lines 40-45).

**Claim 21:** McGee et al disclose that the optical fiber and lumen may include radiopaque materials (col. 5, lines 40-45).

4. Claims 3, 4, 10, 14, 20, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over *McGee et al* and *Crowley et al* as applied to claims 1, 2, 5, 8, 9, 11-13, 19, 32, and 34 above, and further in view of *Morante, Jr.* (US 4,587,972).

McGee et al and Crowley et al substantially disclose all claimed features in claims 3, 4, 10, 14, 20, 33, and 35. However, McGee et al or Crowley et al do not specifically disclose a measurement of vessel and blood characteristic such as hemodynamic characteristics. In *Morante, Jr.*, an intravascular catheter is used to diagnosis and treat blood vessel by measuring hemodynamic characteristics of the blood vessel using optical source or laser energy to assess the level of treatment or therapy required (col. 4, line 42 – col. 5, lines 17). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of *Morante, Jr.*'s hemodynamic characteristic measurement to assess therapy guideline using optics or laser to improve McGee et al and Crowley et al's apparatus where it includes therapy assessment by imaging.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ

May 14, 2006

  
ELENI MANTIS-MERCADER  
PRIMARY EXAMINER